Exhibit B

STUART E. SCHIFFER
Acting Assistant Attorney General
Civil Division
DAVID A. LEVITT
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
TEL: (202) 307-6154
ATTORNEY FOR PLAINTIFF
D.L. 4533

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA Plaintiff, v. ABLE LABORATORIES, INC., a corporation, and MURTY VEPURI, and PAUL MANNING, Individuals, Defendants.	:	Civil Act. No. 91-4916 (AJL)

STIPULATED ORDER AMENDING
AGREED ORDER OF PERMANENT INJUNCTION

WHEREAS, the Food and Drug Administration ("FDA") has concluded, based on findings in establishment inspections conducted after the Agreed Order of Permanent Injunction ("Agreed Order") entered by this Court on April 8, 1992, that the Agreed Order will provide additional protection if amended as herein set forth; and

Plaintiff, the United States, has informed the Defendants that in FDA's opinion its findings constitute violations of the Agreed Order; and

Defendants have denied that FDA's findings constitute violation of the Current Good Manufacturing Practice ("CGMP")

regulations or the Agreed Order, and have informed the FDA of the grounds for such denial; and

Defendants have also alleged that they have taken steps to conform their operations to FDA's concerns; and

The parties wish to avoid further proceedings and have agreed to resolve the matter amicably and for good cause shown;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

The Agreed Order is hereby amended by addition of the following paragraphs to be deemed to be effective as of the date of entry of this Stipulated Amendment:

XV. Defendants Able, Vepuri and Manning shall maintain full compliance with the Agreed Order at all times. To ensure such compliance, the Defendants, within fourteen days of the date of this Order, shall undertake the following measures:

a. Defendant Manning shall discontinue exercising any authority, and henceforth shall exercise no authority, over manufacturing or quality assurance/quality control procedures or personnel at Able or any other drug manufacturing firm affiliated with A.L. Laboratories at which he may be employed. Instead, Manning's sole authority shall be restricted to the area of sales.

b. Defendant Manning shall not represent Able or any other drug manufacturing firm affiliated with A.L. Laboratories at which he may be employed in any manner with regard to purchases by the United States or any of its departments, agencies, or instrumentalities of pharmaceutical products.

c. Defendant Manning shall not engage in any business-required contacts between the sales office of Able or any firm affiliated with A.L. Laboratories and the manufacturing and quality control/quality assurance departments relating to release of products. Defendant Manning's office at Able or any firm affiliated with A.L. Laboratories shall be physically separated from the manufacturing and quality control/quality assurance departments.

d. Defendant Vepuri shall exercise no final authority over manufacturing or quality assurance/quality control procedures or personnel at Able or any other drug manufacturing firm affiliated with A.L. Laboratories at which he may be employed. Instead, Vepuri's work with pharmaceuticals shall be restricted to the areas of research and development.

e. Defendant Vepuri shall not have the final authority over any work at Able or any other drug manufacturing firm affiliated with A.L. Laboratories in support of a New Drug Application or Abbreviated New Drug application, where such work is to be submitted to the United States Food and Drug Administration ("FDA").

f. Defendant Vepuri shall not have the final authority to perform any validation of manufacturing and laboratory processes at Able or any other drug manufacturing firm affiliated with A.L. Laboratories.

g. Defendant Vepuri shall not have the final authority over any business-required contact between research and development and manufacturing and quality control/quality assurance departments at

Able or any other drug manufacturing firm affiliated with A.L. Laboratories at which he may be employed. Defendant Vepuri's office at Able or any firm affiliated with A.L. Laboratories shall be physically separated from the manufacturing and quality control/quality assurance departments.

XVI. Defendant Able shall report in writing to FDA's Newark District Office within 14 days after the entry of this Stipulated Amendment the actions it has taken to comply with the terms of paragraph XV of this Stipulated Amendment.

XVII. If, within a period of two years following entry of this Stipulated Amendment, Defendant Able, Defendant Manning, or Defendant Vepuri is in violation of the Agreed Order for an act or acts occurring after the entry of this Stipulated Amendment as found by the Court or if agreed to by such Defendant, such Defendant shall be individually liable for the amount of $150,000 as a one-time payment of liquidated penalties. The penalty described in this paragraph shall become due and payable immediately to the United States upon agreement between the parties involved or upon a finding by the Court that such Defendant has committed or caused a violation or violations of the Agreed Order. The Court or, by agreement, the parties, may reduce the amount of the penalty imposed under this paragraph in circumstances in which it is determined that the above penalty is not proportional to the nature and scope of the violations so found.

XVIII. The Court hereby imposes individually on each Defendant an additional liquidated penalty of $1,000 per day for any

violation or violations of the Agreed Order by such Defendant for acts occurring after the entry of this Stipulated Amendment as found by the Court or if agreed to by such Defendant. FDA shall notify such Defendant in writing of any such violation as soon as FDA is aware of such violation. Such notification shall specifically refer to this paragraph of this Stipulated Amendment. Any violation of a continuing nature determined to exist as of a particular date shall be deemed to be continuing up to and until the date determined by FDA or the Court that the violation has been remedied. The penalty described in this paragraph is separate from, and payable in addition to, the penalty described in paragraph XVII, and shall become due and payable upon agreement between the parties involved or upon a finding by the Court that such Defendant has committed a violation or violations of the Agreed Order. Penalties imposed under this paragraph are subject to a maximum of $100,000, provided that the parties may agree to, or FDA may petition the Court for, penalties exceeding this maximum if warranted by the nature or extent of the violation. The Court or, by agreement, the parties, may reduce the amount of the penalty imposed under this paragraph in circumstances in which it is determined that the penalty as calculated above is not proportional to the nature and scope of the violations so found.

IXX. Any Defendant shall immediately cease and discontinue manufacturing, packing, labeling, distributing, and dispensing any article of drug, if based on the results of an inspection and/or the analysis of sample(s), the FDA District Director notifies such

Defendant in writing that such Defendant's methods, facilities, and controls for manufacturing, packing, and holding for sale articles of drugs are not established, operated, or administered in substantial compliance with current good manufacturing practice, as set out in 21 CFR Parts 210 and 211; provided, however, that prior to issuing any such notice the District Director shall in writing inform such Defendant of the FDA's tentative decision to invoke this paragraph. If such Defendant within three (3) business days after receipt of such written communication requests, such Defendant shall be given an opportunity to meet with the District Office to determine if Defendant can address the issues raised by such inspection or analysis of sample(s) to FDA's satisfaction without the necessity of issuing such notice. Such notice, when issued, shall specifically cite this paragraph of this Stipulated Amendment and shall specify the alleged violations with reference to the applicable observations from such inspection, the operations and individual products affected, and the manner in which such violations would affect the operations to require cessation. Such cessation of operations may be limited to specific product lines, or may encompass all operations, if necessary. Defendant shall not be required to discontinue operations if a petition is filed with the Court within five (5) business days following receipt of such notice. The foregoing provisions shall not be deemed to prejudice any Defendant's right at any time to request administrative review under 21 C.F.R. §10.75. All parties shall request that any proceedings under this paragraph be addressed by the Court in an

expedited fashion under the standard of review determined appropriate.

XX. Any cessation of operations as described above shall continue until receipt by Defendant of written notification by FDA or the Court that Defendant appears to have corrected the alleged violation. Upon such Defendant's written request, FDA shall, within a reasonable time, determine whether such Defendant appears to have corrected the alleged violation and, if so, issue its written notification permitting resumption of operations.

XXI. This Court retains jurisdiction to enforce the provisions of this Stipulated Amendment and the Agreed Order entered on April 8, 1992, and for purposes of granting such additional relief as may be necessary or appropriate.

XXII. If, within 24 months following the entry of this Stipulated Amendment, the government has not initiated a court action based on alleged violations of this Stipulated Amendment or the Agreed Order, any of the Defendants may submit a request to FDA that FDA join in a petition for relief from this Stipulated Amendment, and may seek such relief, except that if the foregoing 24-month condition is satisfied, the provisions contained in Paragraphs XV and IXX shall automatically terminate.

XXIII. The proceeding to enter this Stipulated Amendment shall not be considered the initiation of a court action based on alleged

violations of the Agreed Order for purposes of Paragraph XIII of the Agreed Order.

Dated this 21st day of May, 1993.

ALFRED J. LECHNER, JR.
United States District Judge

The parties, by themselves and their respective counsel, hereby consent to the terms and conditions of the Stipulated Amendment as set forth above and consent to the entry hereof.

FOR THE UNITED STATES:

STUART E. SCHIFFER
Acting Assistant Attorney General
Civil Division
U.S. Department of Justice

MICHAEL CHERTOFF
United States Attorney

By: Susan C. Cassell

SUSAN C. CASSELL
Assistant United States Attorney
Federal Building
970 Broad Street, Room 502
Newark, New Jersey 07102
(201) 645-2847

David A. Levitt

DAVID A. LEVITT
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

OF COUNSEL:

MARGARET JANE PORTER
Chief Counsel

SUSAN E. KELLEY
Assistant Chief Counsel for
Enforcement
Food and Drug Administration
Rockville, MD 20857
(301) 443-4350

FOR THE DEFENDANTS:

For: William L. Attman
Able Laboratories, Inc.

M Vepuri
Murty Vepuri

Paul B Ma
Paul Manning

Robert H Becker
Kinsey S Reagan
Robert H. Becker, Esq.
Kinsey S. Reagan, Esq.
Kleinfeld, Kaplan & Becker
1140 19th Street, N.W.
Suite 900
Washington, D.C. 20036

Counsel for Able Laboratories, Inc.

George M. Burditt, Esq.
Alan I. Becker, Esq.
Burditt & Radzius
333 West Wacker Drive, Suite 2600
Chicago, Illinois 60606-1218

Counsel for Defendants Vepuri and Manning